III. REMARKS

A. Amendment of Claims

Claims 11, 25, 27, and 35 are to be amended herein, as described above.

Claims 11, 25, and 35 have been amended to change the term "a particle size of 10μm or less" to "a particle size of about 0.5μm to about 10μm". (emphasis added) Basis for this amendment can be found on page 13, line 26 of the Specification.

Claim 27 has been amended to insert the term "bacteria" immediately after "gram positive" in the second line of the claim. (emphasis added) Basis for this amendment can be found on page 4, line 7 of the Specification.

Applicants respectfully submit that none of the amendments to the claims introduced herein adds any new matter to the application.

B. Rejection of Claims 1, 11, 13, 25, 27, and 35, Under 35 U.S.C. 112, Second Paragraph

Claims 1, 11, 13, 25, 27, and 35 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office Action stated that all six of the cited claims are directed to particles having a particle size of 10μm "or less", the term "or less" reading on zero.

Applicants submit that of the six claims cited in this part of the Office action, only claims 11, 25, and 35 are directed to particles having "a particle size of 10μm or less," particles of lincosamide, in this case. Each of those claims is a dependent claim, and each such claim depends from a claim which includes lincosamide particles as an element. Since lincosamide is present in particulate form in each independent claim, the particle size of each lincosamide element in the independent and dependent claims cannot be zero. However, in the interest of directing the subject matter of these dependent claims to particularly preferred embodiments of the invention, each of claims 11, 25, and 35 has been amended herein to add a lower particle size limit of about 0.5 μm.

Claim 27 was also rejected under 35 U.S.C. §112, second paragraph, as being indefinite for using the term "at least one gram positive" without indicating to what that term is referring. Applicants have amended claim 27, herein, to read "at least one gram positive bacteria." (Amended language of claim 27, emphasis added.)

For reasons given herein above, Applicants respectfully submit that claims 1, 11, 13, 25, 27, and 35 meet the requirement of 35 U.S.C. §112, second paragraph. Applicant, therefore, respectfully requests that this rejection be withdrawn.

C. Rejection of Claims 1, 4, 6-7, 11, 13-14, 16, 18, 21, 25, 27-28, 30, and 34 Under 35 U.S.C. §102(a) as Being Anticipated by Linder *et al.* (WO 99/29299)

The Manual of Patent Examining Procedure, Rev. 1, Feb. 2000 (hereinafter, "MPEP"), section 2131 states that:

> "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

The Office Action cites Linder *et al.* as disclosing administration forms for acid-labile compounds, including a suppository for rectal administration. The Office Action also states that Linder *et al.* teaches that in the formulations disclosed therein, the "particle size of the active compound is preferably in the range from 1 to 20 μm, particularly preferably in the range from 3 to 15 μm." (Office Action at p. 3, citing Linder, p. 6). Linder *et al.* is also cited as disclosing rectal suppositories which include "suitable antimicrobially-active ingredients" such as antibiotics, specifically, clindamycin. (*Id.* citing Linder *et al.*, p. 7).

The excerpts of Linder *et al.* cited in the Office Action, and reproduced above, imply that Linder *et al.* discloses suppositories containing an active agent, such as clindamycin, in particulate form. However, Linder *et al.* does not provide any such teaching or suggestion. The term "active compound" is used by Linder *et al.* to refer to "acid-labile active compounds", particularly, acid-labile proton pump inhibitors. (See Linder *et al.*, p. 3, beginning with the third paragraph). The particle size reference cited in the Office Action is a reference to the particle size of the "active compound" defined as described above.

Linder *et al.* makes reference to the production of suppositories comprising acid-labile proton pump inhibitors in combination with antimicrobially active compounds. However, Linder *et al.* does not teach or suggest that any such antimicrobially active compound incorporated into the suppositories disclosed therein is present in particulate form. All of the present pending claims require that lincosamide, an antimicrobially active compound, be present in the form of particles, an element of the invention not disclosed by Linder *et al.* Because it fails to disclose this element of the present invention, Applicant respectfully submits that none of the claims cited in this part of the Office Action are anticipated by Linder *et al.*

For reasons set forth above, Applicants respectfully request that the rejection of claims 1, 4, 6-7, 11, 13-14, 16, 18, 21, 25, 27-28, 30, and 34 Under 35 U.S.C. §102(a) over Linder *et al.* be withdrawn.

D. Rejection of Claims 1, 4, 6-16, 18, 21-28, 30, and 33-36 Under 35 U.S.C. §103(a), Over Linder *et al.*

> "To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)." MPEP 2143.03.

Applicants respectfully submit that the Office Action fails to establish a *prima facie* case of obviousness of any of the above-cited claims over Linder *et al.*, because at least one element of the claimed invention is neither taught nor suggested by the prior art.

Linder *et al.* is cited as disclosing the same teachings discussed in section C of these Remarks, immediately above. Specifically, the reference is cited as disclosing administration forms for acid-labile compounds, including a suppository for rectal administration that includes an "active compound" in particulate form. For reasons set forth above, Applicant respectfully submits that the term "active compound" refers to an acid-labile proton pump inhibitor, and not to compounds such as the lincomycin component of the present claims.

Applicant submits, that it would not have been obvious to one of ordinary skill in the art to make a suppository of the present invention, with a lincomycin present in particulate form, at the time the invention was made. It was conventional, at the time the invention was made, to produce suppositories with drugs, such as antibiotics, dissolved in a solution or melted into the hard fat medium, in order to ensure bioavailability of the drug after administration to a subject. This approach severely limited the amount of drug one could include in any given suppository.

The fact that lincomycin is present in particulate form in the suppositories of the present invention has surprising advantages. First, the particulate form of the lincomycin component of the suppositories allow for a smaller volume of suppository composition to be administered for a given dose, as noted on p. 4, lines 19-20 of the present application. Also, as noted in the present specification, because lincomycin is present in particulate form, "the

stability of the lincomycin is typically better than for a composition where the drug is dissolved in the carrier." (Specification, p. 4, lines 24-27).

For reasons set forth above, Applicants respectfully submit that the Office Action has failed to establish a *prima facie* case of obviousness, under 35 U.S.C. §103(a), of any of claims 1, 4, 6-16, 18, 21-28, 30, and 33-36, over Linder *et al.* Applicants, therefore respectfully request that this rejection be withdrawn.

E. Rejection of Claims 1-36 Under 35 U.S.C. §103(a), Over Linder *et al.* in View of Bergy *et al.* (U.S. Patent No. 3,679,787)

Linder *et al.* is cited in this part of the Office Action as teaching and/or suggesting the same things discussed in sections C and D of the present Remarks section, above. However, the Office Action goes on to note that Linder *et al.* "does not specifically disclose the lincosamide to be lincomycin." (Office Action, p. 5). Bergy *et al.* is cited as providing the teaching of lincomycin, and of a combination of lincomycin and spectinomycin not provided in Linder *et al.*

Applicant submits that, for reasons discussed in sections C and D, above, Linder *et al.* fails to disclose or suggest a suppository formulation containing a lincosamide in particulate form. This missing element is not taught or suggested by Bergy *et al.* alone, or by Linder *et al.* and Bergy *et al.*, when viewed in combination with one another. In view of this fact, therefore, Applicant respectfully submits that the Office Action has failed to set forth a *prima facie* case of obviousness of any of claims 1-36, under 35 U.S.C. §103(a), over Linder *et al.* in view of Bergy *et al.*

For reasons set forth herein above, Applicants respectfully request that this rejection be withdrawn.

IV. SUMMARY

For reasons given above, Applicants respectfully submit that all of the claims remaining pending in the present case (i.e., claims 1-36) are in condition for allowance. Issuance of all the claims is, therefore, requested. The Examiner is invited to contact the undersigned at the telephone number given below, should she wish to discuss the present amendment and suggest changes to the claims in order to further prosecution of the application.

Respectfully submitted,

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Enclosures
Fee transmittal sheet (1 page)